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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,816	09/25/2003	Vernon G. Wong	440882000201	6866

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EXAMINER	
KENNEDY, SHARON E	

ART UNIT	PAPER NUMBER
1615	

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03/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/671,816	WONG ET AL.	
	Examiner	Art Unit	
	Sharon E. Kennedy	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35,37-39,42-47,51,52,55,56,61-67 and 82-95* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35,37-39,42-47,51,52,55,56,61-67 and 82-95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 93-95 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the formulations set forth in Examples 6 and 7, which are examples not containing the release modifiers, does not reasonably provide enablement for the range of implant types now claimed.

Specifically, the weights of the implants now claimed have not been disclosed in Examples 6 and 7. Applicant states that the weight and release profiles are unexpected on page 13, lines 13-16 of the response filed December 11, 2007. Since applicant argues that weight is a critical element in the device not having the release modulator, then applicant cannot at the same time claim a variety of weights that have not been disclosed in those examples without triggering an enablement rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 35, 37-39, 42-47, 51, 52, 55, 56, 61-67, 82-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong '079. Regarding claims 35, 37-39, 42-47, 51, 52, 55, 56, 61-67, 82-92, see the comments set forth in the previous office actions and the "Response to Arguments" section below.

Regarding claims 93-95, see Wong '079, Example 1 and Figure 1A. Wong mixes PLGA and dexamethasone at a ratio of 50/50 to produce six drug delivery systems (DDS) of approximately 100 to 120 μm. The examiner thus concludes that the weight of dexamethasone is 50 to 60 μm. Figure 1A of Wong '079 is examined. At day 21, over 10 μm of drug has been released. This is 20% of the 50 μm. Accordingly, the only difference between claim 93 and Wong '079 is the recitation of the weight of the device. Applicant claims 500 to 1100 pg, while Wong '079 discloses 100 to 120 μm.

Applicant argues that it is surprising that a larger weight drug delivery device would have the same release rate, however, this is not surprising if the drug delivery device is a filament. If it were a sphere, yes, this would be surprising, but not with a filament. A larger sphere has a different surface area to volume ratio calculation (sphere surface area = $4\pi r^2$ and sphere volume = $4/3\pi r^3$). As the radius increases, the volume increases faster than the surface area, providing a drug delivery device that has a slower rate of release. A filament has a much more constant surface area to volume ratio as the length, for example, increases. Theoretically, the weight of a filament could increase by increasing the length while at the same time decreasing the radius of the filament, which would permit a much faster rate of release. These parameters are known in the art and readily envisioned by one of ordinary skill in the art. It's a simple

matter of geometry most of the time, when all other variables are constant. Accordingly, applicant's blanket statements about the relationships between weight and drug release are unconvincing so far.

Accordingly, changing the length of the Wong '079 filament to achieve the higher weight, for example, is obvious to one of ordinary skill in the art. The identical release profile is achieved. Regarding claims 94-95, applicant claims a stepped up release profile and a higher weight range, however, as pointed out thinner, longer filaments could readily provide these release rates. Note also Wong '079 column 7, lines 53-58. "Larger implants will deliver a proportionately larger dose, but depending on the surface to mass ratio, may have a slower release rate."

It is noted that Wong discloses a filament produced by extruding through a 20 gauge orifice (column 8, lines 31-32). The examiner has found various conversion charts indicating various sizes for a 20 gauge orifice, but has not been able to figure out which is accurate. Applicant should enlighten the examiner, and perhaps the claims could be distinguished by claiming the filament diameter, comparing it to the prior art, and pointing out the differences, if any. However, this suggestion is not an indication that any such claim would be considered after Final Rejection.

Response to Arguments

Applicant's arguments filed December 11, 2007 have been fully considered but they are not persuasive.

Regarding claims 35, 37-39, 42-47, 51, 52, 55, 56, 61-67, 82-92, applicant argues that the specification provides clear guidance regarding the "consisting essentially" claim meaning. The examiner does not find applicant's arguments convincing. The instant situation is similar to the factual situation described in the MPEP discussed by the examiner. Applicant's specification must have described what is meant by "consisting essentially of" if applicant wants that phrase to take on a particular meaning to distinguish over the prior art. Providing an example of an implant without a release modifier does not define what is meant by that phrase absent a "clear indication." For example, *In re Herz* construed "consisting essentially of" as eliminating deleterious ingredients for a hydraulic fluid. Nothing in the original specification indicated that the polyvinylpyrrolidinone would be deleterious. Accordingly, the claims were construed as possibly including that ingredient and the claims were unpatentable over the prior art.

See also *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). The court states that "PPG could have defined the scope of the phrase consisting essentially of for purposes of its patent by making clear in its specification what is regarded as constituting a material change in the basic and novel characteristics of the invention." Contrast *AK Steel Corp v. Sollac*, 344 F.3d 1234, 1240-41, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003). Applicant stated that a certain amount of silicon contents would be deleterious, accordingly, the phrase "consisting essentially of" was construed to eliminate that deleterious amount.

Applicant argues that changing the transitional phrase to "consisting essentially of" eliminates the release modifier, however, applicant did not provide any guidance in the original specification that this transitional phrase had this effect. To the contrary, the specification states that release modifiers may be added. Accordingly, the examiner is required by the MPEP to interpret the claims as possibly including the release modifier. Hence, the rejection under 35 U.S.C. 103 is repeated.

Regarding applicant's other comments concerning the rejection, many of applicant's arguments are dedicated to arguing a release modulator free device as contrasted to Wong's Example 1, however, the examiner is not required to interpret the claims without the release modifier. Applicant also argues that the recited implant is to be implanted into the vitreous of the eye, however, the claims are not method claims, and the structure of the device is analyzed. Applicant argues that the examiner did not go through the proper *Graham* rejection steps, instead dismissing the claims in a single paragraph. The examiner incorporated the arguments set forth by the previous examiner, which detailed the grounds of rejection. Wong '079 establishes in columns 7 and 8 that one of ordinary skill in the art is readily able to modify the weight, loading, surface area, etc., to change release profiles. These variable are well-established and even intuitive to ordinary consumers of the device.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sharon E. Kennedy/
Sharon E. Kennedy
Primary Examiner
Art Unit 1615